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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,283	10/12/2001	Wenbin Dang	GPT-C24.01	1639

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/02/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/976,283

Applicant(s)
Dang et al

Examiner
Carlos Azpuru

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1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 4, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above, claim(s) 29-35, 42, and 45-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 15, 16, 19, 23, 28, 36-41, and 60 is/are rejected.
- 7) ☒ Claim(s) 3-14, 17, 18, 20-22, 24-27, 43, and 44 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 & 6 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of the election filed 03/04/03.

Election/Restrictions

Applicant's election with traverse of Group I, formula Vi (claims 1-28, 36-41, 43, and 44) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that examination of all claims would place no undue burden would be placed on the examiner. Additionally, applicant argues that a search for Groups II and III necessarily includes a search for Group I. This is not found persuasive because the classification and search necessary for groups II and II are very different from that of Group I. Group III is a completely different class (handled by another tech center) which involves polymer chemistry. As such, the additional search would entail an undue burden on this examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 29-35, 42, 45--59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-41 are vague and indefinite in not particularly pointing out the structure of monomeric unit. Specifically, the substituents set out as L1, M1, M2, Ms are only set out as "any chemical moiety that does not materially interfere with the biocompatibility of said polymer". This leaves the structure open-ended, with any number of possible ultimate structures possible. Applicant is requested to more adequately set out the claimed structure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 15, 16, 23, and 28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wen et al.

Wen et al disclose a biocompatible polymer having phosphate-based linkages and one or more radiosensitizers (see introduction as well as materials and methods).

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The composition may have up to 25% loading level, and may be in the form of microspheres (see page 66, column 2, paragraph 3). Delivery may be for a period of about 50 days (see Figure 1). The instant claims are anticipated by Wen et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 19, 36-41, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al.

Mao et al disclose the use of a biodegradable polymer of structure VI.

Radiosensitizers are disclosed for inclusion into this composition at col. 20, lines 57-65.

Like other bioactives disclosed for incorporation into the claimed polymeric structure, radiosensitizers may be incorporated at between about 1% to about 65% (see col. 21, lines 6-10). Therefore, it would have been well within the skill of the ordinary practitioner to claim the instant polymer system for delivery of radiosensitizers for their art recognized purpose. Further, the ordinary practitioner would have expected similar therapeutic results in the treatment of tumors given the disclosure of Mao et al. The

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addition of instructions for this composition in order to form a kit is a skill within the ordinary skill of any practitioner, given the clear teaching by Mao et al to use the claimed composition for the same art recognized purpose/There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant drug delivery system for delivery of radiosensitizers and a kit used for that same purpose would have been obvious given the disclosure of Mao et al which sets out the instant monomeric units which are polymerized for delivery of the same radiosensitizing agents.

Claims 3-14, 17, 18, 20-22, 24-27, 43, and 44 are objected to as dependent upon a rejected base claim.

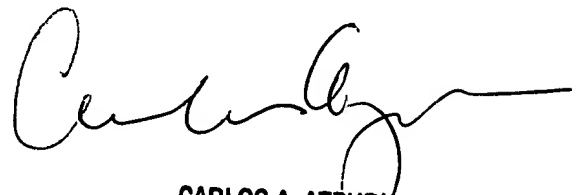
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca
May 1, 2003



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500